29601/107

IX

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

INVITATION TO PAY ADDITIONAL FEES

(PCT Article 17(3)(a) and Rule 40.1)

To:
ROBINS & PASTERNAK LLP
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UNITED STATES OF AMERICA

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ROBINS & PASTERNAK LLP

Applicant's or agent's file reference: 6750-0005.60	Date of mailing (day/month/year): 22/11/2004
International application No.: PCT/US 03/38158	PAYMENT DUE within 45 ~~months~~/days from the above date of mailing
Applicant: IMAGING THERAPEUTICS, INC.	International filing date (day/month/year): 25/11/2003

DOCKETED

1. This International Searching Authority

(i) considers that there are 5 (number of) inventions claimed in the international application covered by the claims indicated ~~below~~/on the extra sheet:

and it considers that the international application does not comply with the requirements of unity of invention (Rules 13.1, 13.2 and 13.3) for the reasons indicated ~~below~~/on the extra sheet:

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1/6/05 (LD)

(ii) [X] has carried out a partial international search (see Annex) [ ] will establish the international search report on those parts of the international application which relate to the invention first mentioned in claims Nos.:

see annex

(iii) will establish the international search report on the other parts of the international application only if, and to the extent to which, additional fees are paid

2. The applicant is hereby **invited**, within the time limit indicated above, to pay the amount indicated below:

EUR 945,00	x	4	=	EUR 3.780,00
Fee per additional invention		number of additional inventions		total amount of additional fees

Or, _____ x _____ = _____

The applicant is informed that, according to Rule 40.2(c), **the payment of any additional fee may be made under protest**, i.e., a reasoned statement to the effect that the international application complies with the requirement of unity of invention or that the amount of the required additional fee is excessive.

3. [ ] Claim(s) Nos. _____ have been found to be unsearchable under Article 17(2)(b) because of defects under Article 17(2)(a) and therefore have not been included with any invention.

Name and mailing address of the International Searching Authority	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Raoul Emme

Form PCT/ISA/206 (July 1992)

Annex to Form PCT/ISA/206
COMMUNICATION RELATING TO THE RESULTS OF THE PARTIAL INTERNATIONAL SEARCH

International Application No
PCT/US 03/38158

1. The present communication is an Annex to the invitation to pay additional fees (Form PCT/ISA/206). It shows the results of the international search established on the parts of the international application which relate to the invention first mentioned in claims Nos.:
see 'Invitation to pay additional fees'
2. This communication is not the international search report which will be established according to Article 18 and Rule 43.

3. If the applicant does not pay any additional search fees, the information appearing in this communication will be considered as the result of the international search and will be included as such in the international search report.

4. If the applicant pays additional fees, the international search report will contain both the information appearing in this communication and the results of the international search on other parts of the international application for which such fees will have been paid.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02/22014 A (ANDRIACCHI THOMAS P ; UNIV LELAND STANFORD JUNIOR (US); STEINES DAVID) 21 March 2002 (2002-03-21) cited in the application page 41 - page 42	1-4
X	PHIDIAS NEWSLETTER NO 6 - RAPID PROTOTYPING IN MEDECINE, 'Online! June 2001 (2001-06), pages 1-8, XP002304725 EDITOR N MOOS DANISH, TECHNOLOGICAL INSTITUTE TEKNOLOGIPARKEN, AARHUS, DK Retrieved from the Internet: URL:http://www.materialise.com/medical/files/ph6.pdf> 'retrieved on 2004-11-08! pages 3, 6-7 (article "Modeling and design '...!" by Taha et al.)	1-4
X	KIDDER J ET AL: "3D model acquisition, design, planning and manufacturing of orthopaedic devices: a framework" PROCEEDINGS OF THE SPIE - ADVANCED SENSOR AND CONTROL-SYSTEM INTERFACE, BOSTON, MA, USA, vol. 2911, 21 November 1996 (1996-11-21), pages 9-22, XP008038390 ISSN: 0277-786X section 4.2	1-4

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

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Annex to Form PCT/ISA/206
COMMUNICATION RELATING TO THE RESULTS
OF THE PARTIAL INTERNATIONAL SEARCH

International Application No
PCT/US 03/38158

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	CARR J C ET AL: "SURFACE INTERPOLATION WITH RADIAL BASIS FUNCTIONS FOR MEDICAL IMAGING" IEEE TRANSACTIONS ON MEDICAL IMAGING, IEEE INC. NEW YORK, US, vol. 16, no. 1, 1 February 1997 (1997-02-01), pages 96-107, XP000685494 ISSN: 0278-0062 abstract	1-4
X	US 2002/059049 A1 (BRADBURY THOMAS J ET AL) 16 May 2002 (2002-05-16) paragraph '0057! paragraph '0060! - paragraph '0062! paragraph '0115!	1-4

Form PCT/ISA/206 (Annex, continuation sheet) (July 1992; reprint January 2004)

INVITATION TO PAY ADDITIONAL FEES

International application No.
PCT/US 03/38158

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-4

in the context of designing an articular implant, reconstructing in an image the dimensions of diseased cartilage to correspond to normal cartilage, with a parametric surface

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2. claims: 5-7

in the context of designing an articular implant, reconstructing in an image the dimensions of diseased cartilage to correspond to normal cartilage, via a morphological closing operation

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3. claims: 8-17, 27-38

evaluating the image-fit of an articular repair system into a joint

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4. claims: 18-26, 65-83, 86-102

surgical tool for preparing a joint to receive an implant, the tool comprising one or more surfaces or members that conform to the shape of the articular surfaces of the joint.

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5. claims: 40-64

customizable implant configured for placement between joint surfaces

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1. Prior art:

Reference is made with D1 to following document cited in the application:
D1: WO02/22014

D1 discloses claim 1, which is therefore not novel.
In fact, D1 discloses:
a method of designing an articular implant
(see D1, page 41, line 13, to page 42, line 14)
comprising the steps of
- obtaining an image of a joint, wherein the image includes at least one of normal cartilage and diseased cartilage;
(see D1, page 41, lines 17-21)
- reconstructing dimensions of the diseased cartilage surface to correspond to normal cartilage ;
(see D1 page 41, lines 24-30 and p. 42, lines 7-10)

- and designing the articular implant to match the dimensions of the reconstructed diseased cartilage surface or an area greater than the diseased cartilage surface.
(see D1, page 42, lines 7-10)

Concerning claim 2, D1 discloses the additional feature of claim 2 of the image being an MRI-image (see D1, page 41, lines 17-21). Claim 2 is therefore not novel
Moreover, the other imaging modalities recited in claim 2 are standard in the field of medical imaging, and the skilled person would implement the method of claim 1 to images of these modalities without the exercise of inventive skills. Two of these alternative imaging modalities, namely CT and ultrasound, are cited also in D1 as examples of alternative imaging modalities (see D1, p.21, lines 11-15). Claim 2 as a whole is therefore not taken into consideration in the assesment of the special technical features (STF) of the alleged inventions.

2. Special technical features (STF) and associated objective problems:

2.1 First subject:
The STF of the first subject consist in the features of claim 3. The objective problem solved by these features with respect to D1, regards the improvement of reconstruction of cartilage in an image.

2.2 Second subject:
The STF of the second subject consist in the features of claim 5. The objective problem solved by these features with respect to D1, regards the improvement of reconstruction of cartilage in an image.

2.3 Third subject:
The STF of the third subject consist in the features of claim 8. The objective problem solved by these features with respect to D1, regards the quality check and the optimal choice of the implant.

2.4 Fourth subject:
The STF of the fourth subject consist in the features of claim 18. The objective problem solved by these features with respect to D1, regards providing a surgical tool for preparing a joint to receive an implant.

2.5 Fifth subject:
The STF of the fifth subject consist in the features of claim 40 or 41. The objective problem solved by these features with respect to D1, regards the construction of a joint implant.

3. Conclusion:

The STF of the different subjects are obviously not the same, and can be implemented independently from each other. Moreover, the objective problems, when compared in a pairwise manner, don't show any correspondence allowing to identify a common general inventive concept. This applies in particular to the common problem of the first and the second subject, which is of obvious nature (improvement of a feature of D1) and is the basis for two completely independent alternative

solutions.
The application therefore does not comply with the requirements of Rule 13 PCT.

4. Additional remark:

The application relates to a plurality of inventions, or groups of inventions, in the sense of Rule 13.1 PCT. They have been divided as defined above. If the applicant pays additional fees for one (or more) not yet searched group(s) of invention(s), then the further search(es) may reveal further prior art that gives evidence of a further lack of unity 'a posteriori' within one (or more) of the not yet searched group(s). In such a case only the first invention in this (each of these) group(s) of inventions, which is considered to lack unity of invention, will be the subject of a search.No further invitation to pay further additional fees will be issued. This is because Article 17(3)(a) PCT stipulates that the ISA shall establish the International Search Report on those parts of the international application which relate to the invention first mentioned in the claims ('main invention') and for those parts which relate to inventions in respect of which the additional fees were paid. Neither the PCT nor the PCT guidelines provide a legal basis for further invitations to pay further additional search fees (W17/00, point 11 and W1/97, points 11-16).

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 206

Continuation of Box 3.

Claim(s) not searched:
39, 84-85

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

Patent Family Annex

...ormation on patent family members

...ternational Application No
PCT/US 03/38158

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 0222014 A	21-03-2002	AU 9088801 A	26-03-2002
		CA 2425120 A1	21-03-2002
		EP 1322225 A1	02-07-2003
		WO 0222014 A1	21-03-2002
		US 2004167390 A1	26-08-2004
US 2002059049 A1	16-05-2002	US 2002007294 A1	17-01-2002
		AU 4993501 A	23-10-2001
		EP 1312025 A2	21-05-2003
		WO 0177988 A2	18-10-2001